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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,655	07/31/2001	Peter Boekstegers	07883.0046	1083

7590

08/07/2003

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EXAMINER

THANH, QUANG D

ART UNIT

PAPER NUMBER

3764

DATE MAILED: 08/07/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

EC

Office Action Summary

Application No.

09/917,655

Applicant(s)

BOEKSTEGERS ET AL.

Examiner

Quang D. Thanh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10-22 and 24-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10-22 and 24-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on 06/24/2003 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of U.S. Patent No. 6,290,728 B1, has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3-8, 10-22, 24-35 rejected under 35 U.S.C. 103(a) as being unpatentable over Tweden et al. (6,406,488) in view of Eno et al. (6,409,697 B2).
4. Re claims 1 and 29, Tweden discloses a device and a method of providing blood flow directly from a left ventricle of a heart chamber to a coronary artery (see abstract), comprising: providing a stent 10 (portions 13 and 14) (fig. 1) having sufficient strength to resist deformation from contractile cardiac forces (col. 2, lines 49-51) and flexibility in a compressed and a deployed state to permit passage to a myocardial site and remain patent when implanted (figs. 1-6, col. 3, lines 23-38); the stent includes a flared end 12 (fig. 1), and a covering 30 on an inner surface portion and outer surface portion of the stent (fig. 2, col. 4, lines 12-18); delivering the stent percutaneously in a compressed state into a passage at the myocardial site (col. 3, lines 34-36); and expanding the stent

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to deploy it in the passage (fig. 5-6, col. 3, lines 34-36) such that the flared end 12 seats around an end of the passage (fig. 1), except that Tweden's stent is an L-shaped and is not substantially straight. However, Eno teaches a transmyocardial implant 10 (fig. 1) comprising a straight elongate cylindrical tube or conduit 11 having a flared end 22/12. Eno also suggests that while the tube 11 is preferably straight, the tube 11 could be bent so that the direction of blood from end 12 is not perpendicular to the arterial blood flow direction A (col. 5, lines 4-7). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to substitute the L-shaped stent of Tweden with the straight stent of Eno, as suggested and taught by Eno, since both are well known in the art as equivalent means for medical implant stent. Moreover, it would have been an obvious matter of design choice to modify the Tweden's device, to have a substantially straight stent, since applicant has not disclosed that having the substantially straight stent solves any stated problem or is for any particular purpose and it appears that the device would perform equally well with either designs. Furthermore, absent a teaching as to criticality that the stent is substantially straight, this particular arrangement is deemed to have been known by those skilled in the art since the instant specification and evidence of record fail to attribute any significance (novel or unexpected results) to a particular arrangement. In re Kuhle, 526 F.2d 553,555,188 USPQ 7, 9 (CCPA 1975).

5. Re claims 3-4, 10-12, 15-16, 24-26, and 30-31 Tweden discloses (claims 3 and 30) the covering 30 includes expanded PTFE material (col. 5, lines 2-3); (claims 4 and

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31) wherein the covering covers substantially all of an inner and outer surface of the stent (col. 4, lines 50-54, fig. 2); (claims 10 and 24) the flared end 12 is placed in the passage to face the coronary vessel (fig.1); (claims 11-12 and 25-26) the coronary vessel is a coronary artery 82 and the heart chamber is a left ventricle 83 (fig. 1); (claims 15-16) delivering the stent includes delivering the stent percutaneously in a compressed state into a passage at the myocardial site (col. 3, lines 34-36).

6. Re claims 5-8,17-22, and 32-35, Tweden also discloses the stent including a hemocompatible and anti-thrombogenic agent such as heparin coating over the covering on the inner surface of the stent (col. 4, lines 28-31).

7. Re claims 13-14 and 27-28, with respect to the limitation "partial blockage", Tweden discloses the myocardial site is distal to a coronary blockage 81 (fig. 1), which appears to be a partial blockage. Alternatively, if blockage 81 is not viewed to be a partial blockage then it would be obvious for a coronary blockage to be either total or partial blockage and in either case the device and method taught by Tweden still apply.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang D. Thanh whose telephone number is (703) 605-4354. The examiner can normally be reached on Monday-Thursday & alternate Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (703) 308-2698. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1148.

Quang D. Thanh
Patent Examiner
Art Unit 3764

QT



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